

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
MONROE DIVISION**

ALICIA SMITH, *et al.*,

Plaintiffs,

V.

UNITED STATES HEALTH  
RESOURCES AND SERVICES  
ADMINISTRATION, *et al.*,

Defendants.

Case No. 3:23-cv-01425

Judge Elizabeth E. Foote

Magistrate Judge Kayla D. McClusky

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR  
MOTION TO DISMISS THE SECOND AMENDED COMPLAINT**

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## INTRODUCTION

In the Public Readiness and Emergency Preparedness (PREP) Act, Congress struck a careful balance to ensure access to vital countermeasures in response to public health emergencies. Concerned that the specter of litigation could impede development of and access to such countermeasures, Congress granted broad immunity in connection with the provision of countermeasures covered by a PREP Act declaration by the Secretary of Health and Human Services. At the same time, Congress provided that where administration of a covered countermeasure directly causes serious physical injury or death, the injured person or her survivors can seek compensation in a no-fault administrative claims process — the Countermeasures Injury Compensation Program (CICP). Plaintiffs ask this Court to unravel this statutory scheme by invalidating and enjoining both the PREP Act’s liability immunity and the operation of the CICP, claiming that the program violates their rights to due process and a jury trial under the Fifth and Seventh Amendments. But they fall well short of stating a claim under either provision.

Plaintiffs’ procedural due process claim fails at the outset because they cannot establish that the PREP Act’s immunity provisions deprived them of a protected property interest. It is well established that there is no vested interest in the continued operation of any rule of common law. *See Ducharme v. Merrill-National Labs.*, 574 F.2d 1307, 1309 (5th Cir. 1978) (per curiam); *Leuz v. Sec’y of Health & Hum. Servs.*, 63 Fed. Cl. 602 (2005). Rather, consistent with due process, Congress can enact (and often has enacted) statutes that prospectively abrogate or offer immunity for common-law causes of action. Plaintiffs likewise do not allege that Defendants infringed any purported liberty interest in earning an occupation or informed consent to medical care.

Even if the PREP Act implicated a protected interest, Plaintiffs fail to show any constitutional inadequacy in CICP’s procedures. Instead, they raise a series of criticisms of the CICP, without explaining how any of them violate their constitutional rights. Beyond that

fundamental flaw, most of Plaintiffs’ criticisms of the CACP are refuted by their own allegations, the materials cited in their Complaint, and the governing statutes and regulations.

Plaintiffs’ substantive due process claim fares no better. Substantive due process is limited to protecting “deeply rooted” “fundamental rights and liberties” that are “implicit in the concept of ordered liberty.” *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997). Plaintiffs identify no such rights at stake. Rather, their substantive due process claim is merely a repackaging of their failed procedural due process claim.

Plaintiffs’ claim to a jury trial right in pursuing compensation from the federal government also fails. “When the sovereign waives immunity it may attach any conditions (including no right to trial by jury) to its consent.” *Ducharme*, 574 F.2d at 1311. Therefore, “if Congress waives the Government’s immunity from suit, . . . the plaintiff has a right to a trial by jury only where that right is one of the terms of the Government’s consent to be sued. Like a waiver of immunity itself, [it] must be unequivocally expressed.” *Lehman v. Nakshian*, 453 U.S. 156, 160 (1980). Plaintiffs identify no such waiver here, much less an unequivocal one.

As clear as it is that Plaintiffs’ claims fail, the Court need not even reach the merits, as their case suffers from a more fundamental problem: lack of standing. Plaintiffs claim to have been harmed by the PREP Act’s immunity provisions, but they fail to allege that they would bring tort claims in the absence of PREP Act immunity, nor do they show that such claims would be timely or that federal jurisdiction would exist over such claims (as would be necessary to trigger the Seventh Amendment). Plaintiffs ask this Court to enjoin Defendants from “enforcing those provisions of the PREP Act which create the scheme providing liability protection and a compensation process for COVID-19 vaccines.” 2d Am. Compl., Prayer for Relief, § 2, but PREP Act immunity is not “enforced” by Defendants; it was granted by Congress, and is asserted as a

defense in litigation by tort defendants who are not parties here and would not be bound by this Court's judgment. Therefore, the requested injunctive relief would not redress Plaintiffs' claimed injuries but instead would leave them worse off, with no ability to bring tort claims against immune defendants and no ability to pursue administrative claims through the CICP.

Thus, whether for lack of standing or failure to state a claim, this case should be dismissed.

## **BACKGROUND**

### **I. The Public Readiness and Emergency Preparedness (PREP) Act**

In 2005, Congress enacted the PREP Act, Pub. L. No. 109-148, 119 Stat. 2680, Division C (2005) (codified at 42 U.S.C. §§ 247d-6d, 247d-6e), to encourage the development and deployment of medical countermeasures during public health emergencies.<sup>1</sup> Two aspects of the PREP Act operate in tandem to achieve this result: broad immunity from tort liability for those involved in making covered countermeasures available, and an opportunity for those injured by covered countermeasures to seek compensation from the federal government through a no-fault administrative claims program, the Countermeasures Injury Compensation Program (CICP).

The PREP Act's provisions come into effect when the Secretary of Health and Human Services issues a declaration after making the determination that a disease, health condition, or other threat to health constitutes a public health emergency or there is a credible risk that it may in the future constitute such an emergency and that the manufacture, testing, development, distribution, administration, or use of one or more countermeasures is covered. 42 U.S.C. § 247d-6d(b)(1). In deciding whether to issue such a declaration with respect to a countermeasure, "the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing,

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<sup>1</sup> See Cong. Rsch. Serv., Compensation Programs for Potential COVID-19 Vaccine Injuries 2 (Oct. 20, 2021), <https://crsreports.congress.gov/product/pdf/LSB/LSB10584>.

promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.” *Id.* § 247d-6d(b)(6). Such a declaration triggers immunity from liability “with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure,” with the exception of claims for willful misconduct. *Id.* § 247d-6d(a)(1).<sup>2</sup>

## **II. The Countermeasures Injury Protection Program (CICP)**

### **A. Applicable Statutes and Regulations**

The PREP Act authorized the Secretary to create the Countermeasures Injury Compensation Program (CICP). Under the CICP, those who allege they have been seriously injured by, and survivors who allege that a decedent died from, the administration or use of a covered countermeasure can bring a claim for compensation from the federal government in a no-fault administrative claims process. *See generally id.* § 247d-6e. Compensation is available under the statute for serious physical injury or death “directly caused by the administration or use of a covered countermeasure pursuant to such declaration.” *Id.* § 247d-6e(a), (b)(1). A determination “as to the direct causation of a covered injury” must be “based on compelling, reliable, valid, medical and scientific evidence.” *Id.* § 247d-6e(b)(4). Congress imposed a one-year deadline for filing claims. *Id.* (incorporating procedural provisions from 42 U.S.C. § 239a); *id.* § 239a(d).

HHS and its component, the Health Resources and Services Administration (HRSA), promulgated regulations establishing and governing the CICP. *See* 42 C.F.R. Part 110. The regulations provide that an individual who suffered a serious injury directly caused by a covered

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<sup>2</sup> That immunity extends to the United States and those who produce, sell, plan programs for, prescribe, administer, or dispense those covered countermeasures. *Id.* § 247d-6d(i)(2). As an exception to this immunity, the Act provides “an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct.” *Id.* § 247d-6d(d)(1).

countermeasure, or the survivor of a decedent whose death was directly caused by an injury caused by a covered countermeasure, can file a claim for compensation. 42 C.F.R. § 110.10(a). The claim generally must be filed within one year of administration or use of the covered countermeasure. *Id.* § 110.42(a). A requester must submit a request package with the documentation necessary to determine eligibility, such as medical records and (in a claim for death benefits) the death certificate and documentation that the requester is an eligible survivor. *Id.* §§ 110.41, 110.50, 110.51, 110.52.

## **B. The Process For Reviewing CICP Claims**

CICP's regulations govern many aspects of the determination of CICP claims, *see generally* 42 C.F.R. Part 110, and the process for submission of CICP claims is also outlined on the CICP's website. HRSA, Countermeasures Injury Compensation Program (CICP) Filing Process, <https://www.hrsa.gov/cicp/filing-process>. If a requester has not submitted sufficient documentation to determine whether the requester is eligible for compensation, the program will inform the requester and give the requester an opportunity to submit the necessary documentation. 42 C.F.R. § 110.71. The CICP's medical staff conduct an initial medical review of request packages. <https://www.hrsa.gov/cicp/filing-process>. The Director of the Division of Injury Compensation Programs (DICP) (currently Commander George Reed Grimes, M.D., M.P.H.) then makes determinations concerning whether a requester is eligible for compensation. *See* 2d Am. Compl. Ex. 5 (decision letter signed by Dr. Grimes). If the requester is eligible for compensation, the program will inform the requester what documentation the requester must submit to establish the amount of compensation. *See* 42 C.F.R. § 110.60; *see also id.* §§ 110.80-110.82 (regulations setting forth how benefits are calculated). The Director then determines the amount of benefits and notifies the requester in a written decision letter. *See id.* § 110.73. If the Director determines that the requester is not eligible for compensation, the Director will issue a written decision letter

to the requester, explaining the basis for the disapproval. *See id.* § 110.74; *see, e.g.*, 2d Am. Compl. Ex. 5. Therefore, regardless of how the claim is resolved, the requester will receive a written decision letter setting forth the basis of the Director's determination.

A requester may seek reconsideration, of either a determination that the requester is not eligible for benefits or the amount of such benefits, by submitting a letter seeking reconsideration within 60 days of the decision on the requester's claim. 42 C.F.R. § 110.90(a). A qualified panel of medical reviewers, independent of the CICP, reviews the recommendation request (including the documentation concerning the claim) and makes a recommendation as to whether the request for reconsideration should be granted. *Id.* § 110.90(c). The Associate Administrator of the HSB reviews the panel's recommendation and makes a final written determination, which is sent to the requester or his or her representative. *Id.* § 110.90(c). The Associate Administrator's determination is not subject to further administrative or judicial review. *See* 42 C.F.R. § 110.90(c); 42 U.S.C. § 247d-6e(b)(4); 42 U.S.C. § 239a(f)(2).

### **III. Plaintiffs' Allegations**

Plaintiffs are five individuals who allege that they received a COVID-19 vaccine and have suffered injuries that they contend were caused by the vaccine. Plaintiff Carolina Bourque received COVID-19 vaccine doses on March 17, 2021, and June 17, 2021. 2d Am. Compl. ¶¶ 25, 27. She alleges that she suffered injuries immediately after receiving each shot. *Id.* ¶¶ 25, 27. She filed a CICP claim during March 2022. *Id.* ¶ 33. She was informed by a CICP representative on February 8, 2023, that CICP was lacking her medical records. *Id.* She does not allege what subsequent steps she took, if any, to ensure that CICP had the medical records necessary to resolve her claim. Her claim remains pending. *Id.* ¶ 35.

Plaintiff Emma Burkey received a COVID-19 vaccine dose on March 20, 2021. *Id.* ¶ 37. She alleges that she began to suffer serious injuries shortly after receiving the vaccine. *Id.* ¶¶ 38-

45. She submitted a CICIP claim in November 2021. *Id.* ¶ 54. On December 20, 2023, the day before Plaintiffs filed the Second Amended Complaint, the Director of the DICI issued a decision letter to Ms. Burkey's mother (who submitted the claim on Ms. Burkey's behalf) determining that Ms. Burkey had suffered an injury that was eligible for compensation and requesting additional documentation to determine the amount of benefits.<sup>3</sup>

Plaintiff Christopher Cody Flint received a COVID-19 vaccine dose on February 1, 2021. *Id.* ¶ 56. He alleges that he suffered injuries shortly after receiving the vaccine. *Id.* ¶¶ 56-58. He filed a CICIP claim on April 25, 2021. *Id.* ¶ 61. His claim was denied on May 25, 2022 in a letter signed by Dr. Grimes, the Director of the DICI. *Id.* ¶ 61; Ex. 5. The letter concluded that "[t]he compelling, reliable and valid medical and scientific evidence does not support a causal association between the Pfizer COVID-19 vaccine and" Flint's injuries. *Id.* Ex. 5. On June 15, 2022, Flint requested reconsideration. *Id.* ¶ 63. His request for reconsideration was denied on January 18, 2023. *Id.*

Plaintiff Michelle Zimmerman received a COVID-19 vaccine dose on March 14, 2021. *Id.* ¶ 67. She alleges that she immediately began suffering serious injuries. *Id.* She filed a CICIP claim on October 1, 2021. *Id.* ¶ 74. Her claim remains pending. *Id.* ¶ 79.

Plaintiff Jessica Krogmeier received a COVID-19 vaccine dose on September 3, 2021. *Id.* ¶ 82. She alleges that she began suffering injuries immediately after receiving the vaccine. *Id.* ¶ 84. Krogmeier submitted a CICIP claim in September 2021. *Id.* ¶ 91. Although she alleges that her physicians submitted medical records, she was informed by a CICIP representative on February 9, 2023, that the CICIP was lacking her medical records, and that the CICIP could not progress with

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<sup>3</sup> Defendants have not attached to this filing the decision letter, which contains medical information about Ms. Burkey, but would be willing to file it under seal if requested by the Court.

processing her claim without the medical records. *Id.* ¶ 92. She does not allege what steps she subsequently took, if any, to ensure that CICP had her medical records.

To summarize, one Plaintiff (Ms. Burkey) received a decision letter indicating that her claim was compensable approximately two years after submitting her claim. One Plaintiff (Mr. Flint) had a claim denied 13 months after submission and a reconsideration request denied seven months after submission. Two Plaintiffs (Ms. Bourque, Ms. Krogmeier) were informed by CICP representatives that CICP did not have medical records needed to process their claims but do not allege what subsequent steps, if any, they took to ensure that CICP had or received those records. And the remaining Plaintiff (Ms. Zimmerman) had a claim pending for just over two years at the time of the Second Amended Complaint.

### LEGAL STANDARD

“Federal Rule of Civil Procedure 12(b)(1) allows a defendant to move for the dismissal of a plaintiff’s claims for lack of subject matter jurisdiction.” *Strange v. Wal-Mart Inc.*, No. CV 18-0325, 2018 WL 2269919, at \*1 (W.D. La. May 16, 2018). “The plaintiff bears the burden of establishing subject matter jurisdiction.” *Id.* When a defendant raises a “facial attack” on the court’s subject matter jurisdiction based on the pleadings, a court “look[s] to the sufficiency of the allegations in the complaint” to “determine whether [the] complaint sufficiently alleges the necessary jurisdictional facts.” *Id.* at \*2 (quoting *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981)).

“In order to survive a motion to dismiss brought under Rule 12(b)(6), a plaintiff must ‘state a claim to relief that is plausible on its face.’” *Joyner v. Kansas City S. R.R. Co.*, No. CV 22-180, 2022 WL 1548097, at \*1 (W.D. La. May 16, 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Although “[t]he Court must accept as true all of the factual allegations in the complaint,” it “is ‘not bound to accept as true a legal conclusion couched as a factual allegation.’” *Id.* (quoting

*Papasan v. Allain*, 478 U.S. 265, 286 (1986)). “A court may dismiss an otherwise well-pleaded claim if it is premised upon an invalid legal theory.” *Id.* In resolving a Rule 12(b)(6) motion to dismiss, a court “may consider the complaint, its proper attachments, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” *Doe v. United States*, 853 F.3d 792, 800 (5th Cir. 2017) (citations and quotations omitted).

## ARGUMENT

### I. Plaintiffs Fail To Plead A Basis For Standing

“[T]o establish standing, a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief.” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). “The plaintiff must clearly allege facts at the pleading stage establishing all three criteria.” *Satanic Temple Inc. v. Young*, No. 4:21-CV-00387, 2023 WL 4317185, at \*2 (S.D. Tex. July 3, 2023). “[S]tanding is not dispensed in gross. To the contrary, a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought.” *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017) (citations and quotations omitted).

Plaintiffs fail to adequately plead a basis for standing in several respects. Although they claim to have been injured because the PREP Act provides immunity for certain tort claims, they do not allege that absent PREP Act immunity, they would actually bring such tort claims—only that they “could” do so. *See* 2d Am. Compl. ¶¶ 132, 144. But they do not articulate which causes of action they would bring, under which law, against which defendants, and when. Such allegations of “‘some day’ intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the ‘actual or imminent’ injury that [the Supreme Court’s] cases require.” *Lujan v. Defs. of Wildlife*, 504 U.S.

555, 564 (1992). It is not at all clear that any such claims would be timely, and it is therefore unclear whether any claimed injury deriving from PREP Act immunity is redressable.<sup>4</sup> To the extent Plaintiffs claim to have been harmed by an alleged deprivation of a right under the Seventh Amendment to a jury trial in federal court<sup>5</sup> for their tort claims, they do not show that federal courts would have subject-matter jurisdiction over their tort claims. Plaintiffs also lack standing to challenge the CICP’s one-year filing deadline; because Plaintiffs allege they complied with that filing deadline, *see* 2d Am. Compl. ¶¶ 33, 54, 61, 74, 91, they cannot show they were harmed by that deadline in any way.

Furthermore, Plaintiffs lack standing to seek their requested injunctive relief because such relief would not redress their alleged injuries. Plaintiffs ask for injunctive relief prohibiting Defendants “from enforcing those provisions of the PREP Act, which create the scheme providing liability protection and a compensation process for COVID-19 vaccines.” *Id.*, Prayer for Relief, § 2. Plaintiffs appear to believe that if this Court entered such an injunction, they would be free to file tort claims against potential defendants unencumbered by liability immunity, but that is incorrect.

Liability immunity under the PREP Act is not “enforc[ed]” by Defendants. It is a benefit granted by Congress to potential defendants in a statutory provision stating that subject to applicable limitations, “a covered person shall be immune from suit and liability under Federal and State law with respect to all claims” relating to the administration of covered countermeasures. 42 U.S.C. § 247d-6d(a)(1). In litigation covered by PREP Act immunity, defendants assert the

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<sup>4</sup> For example, Ms. Bourque is a Louisiana resident who alleges that she received COVID-19 vaccine doses in 2021. *See* 2d Am. Compl. ¶¶ 16, 26-27. Louisiana applies a one-year prescriptive period for most tort claims. La. Civ. Code Ann. art. 3492.

<sup>5</sup> “The Seventh Amendment . . . governs proceedings in federal court, but not in state court . . . .” *Gasperini v. Ctr. For Humanities, Inc.*, 518 U.S. 415, 432 (1996).

PREP Act as a defense, and if immunity applies, the court dismisses the lawsuit. *See, e.g., Bird v. State*, 537 P.3d 332, 336-37 (Wyo. 2023) (affirming decision granting summary judgment to defendant on the basis of PREP Act immunity); *M.T. as next friend of M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1070-71 (Kan. App. 2023) (directing dismissal of all claims pursuant to PREP Act immunity). Potential defendants to such tort claims are not parties here and would not be bound by an injunction entered by this Court. *See Taylor v. Sturgell*, 553 U.S. 880, 893 (2008) (recognizing the general rule that nonparties to litigation are not bound by judgments).

Therefore, even if the Court entered the injunction requested by Plaintiffs, Plaintiffs still would not be able to bring tort claims against potential defendants, because those defendants would be entitled to assert PREP Act immunity as a defense. However, the requested injunction would preclude Defendants from “enforcing . . . the compensation process for COVID-19 vaccines,” 2d Am. Compl, Prayer for Relief, § 2, meaning the CICP claims process. Plaintiffs would be left worse off, with no ability to pursue tort claims and no ability to pursue administrative compensation claims under the CICP. Because the requested injunctive relief would not redress Plaintiffs’ alleged injuries, they lack standing to request it.

## **II. Plaintiffs Fail To State A Claim Upon Which Relief May Be Granted**

### **A. Plaintiffs Fail To State A Procedural Due Process Claim**

The PREP Act’s grant of liability immunity in the context of countermeasures in public health emergencies, and the CICP’s provision of an administrative path to compensation for countermeasure-related injuries, do not violate Plaintiffs’ right to procedural due process. Plaintiffs’ contrary arguments fail as a matter of law.

The Due Process Clause of the Fifth Amendment provides, “nor shall any person . . . be deprived of life, liberty, or property, without due process of law.” U.S. Const. amend. V.<sup>6</sup> Courts “examine procedural due process questions in two steps: the first asks whether there exists a liberty or property interest which has been interfered with by the [government]; the second examines whether the procedures attendant upon that deprivation were constitutionally sufficient.” *Ky. Dep’t of Corr. v. Thompson*, 490 U.S. 454, 460 (1989) (citation omitted). At the first step, a court “must look to see if the interest is within the Fourteenth Amendment’s protection of liberty and property” in order “to determine whether due process requirements apply in the first place.” *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 570-71 (1972). Plaintiffs’ claim fails at both steps. They fail to allege that they have been deprived of a protected liberty or property interest, and even if they had, they fail to allege that the CICP’s procedures are constitutionally insufficient.

# **1. Plaintiffs Have Not Been Deprived Of A Protected Liberty Or Property Interest**

Plaintiffs’ procedural due process claim fails at the threshold because they have not shown a deprivation of a protected liberty or property interest. Plaintiffs claim that four liberty or property interests are at stake, but in each case, their claim fails as a matter of law.

*First*, Plaintiffs claim that the PREP Act deprives them of a protected property interest because it “extinguished Plaintiffs’ common law tort claims” and replaced them with an administrative compensation program. 2d Am. Compl. ¶ 136. But the PREP Act granted immunity for claims relating to covered countermeasures long before Plaintiffs were injured. As

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<sup>6</sup> The Fourteenth Amendment similarly provides: “nor shall any State deprive any person of life, liberty, or property, without due process of law.” U.S. Const. amend. XIV. Some of the cases discussed in this section involve analysis of the Fourteenth Amendment’s Due Process Clause as applied to state action. “Because the Due Process Clauses use the same language and guarantee individual liberty in the same way, . . . the standards developed in the Fourteenth Amendment context must govern under the Fifth Amendment.” *Douglass v. Nippon Yusen Kabushiki Kaisha*, 46 F.4th 226, 238 (5th Cir. 2022).

the Fifth Circuit has repeatedly held, litigants have no vested right in the continuation of a long-ago abrogated rule of common law, and so Plaintiffs were not deprived of any property interest protected by the Due Process Clause.

In *Keller v. Dravo Corp.*, 441 F.2d 1239 (5th Cir. 1971), the Fifth Circuit upheld against a due process challenge the Longshoremen's and Harbor Workers' Compensation Act, which "makes management immune from damage suits for its maritime torts against repair yard workers," and substitutes an administrative workers' compensation claim. *Id.* at 1241. The court rejected the argument that the workers had a protected property interest in tort claims, explaining that the Supreme Court has held that "[a] person has no property, no vested interest, in any rule of the common law. . . . Rights of property which have been created by the common law cannot be taken away without due process; but the law itself, as a rule of conduct, may be changed at the will . . . of the legislature, unless prevented by constitutional limitations." *Id.* at 1242 (quoting *Mondou v. New York, New Haven & Hartford R.R. Co.*, 223 U.S. 1, 50 (1912)). As the Fifth Circuit explained, "one cannot be heard to question the sufficiency of due process if the rule of law, which merely held the potential to create a property right, was changed before any right vested." *Id.*

The Fifth Circuit later reaffirmed the principle that a statute that prospectively provides immunity from tort claims does not deprive litigants of a protected property interest in *Ducharme v. Merrill-National Laboratories*, 574 F.2d 1307 (5th Cir. 1978) (per curiam), a case that, like this one, involved a statute that provided immunity from tort claims for vaccine injuries. *Ducharme* involved the Swine Flu Act, a statute enacted in 1976 that abrogated tort claims arising out of swine flu vaccinations and replaced them with an exclusive cause of action against the federal government, with no right to a jury trial. *Id.* at 1309. Rejecting plaintiffs' claim that the act violated the Due Process Clause because it "abrogated plaintiffs' cause of action" against the

manufacturer under Louisiana law, the Fifth Circuit held that “[i]t is well settled that a plaintiff has no vested right in any tort claim for damages under state law.” *Id.* Because “[p]laintiffs’ cause of action against the manufacturer did not arise until after passage of the Swine Flu Act,” they “had no prior vested right in a cause of action.” *Id.* at 1310. The same is true here of Plaintiffs’ tort claims and the PREP Act. These Fifth Circuit decisions are binding and compel rejection of Plaintiffs’ due process claim.

Furthermore, many other courts are in accord. Like *Ducharme*, several courts (including the Eighth Circuit) rejected due process challenges to the Swine Flu Act.<sup>7</sup> More recently, the Court of Federal Claims upheld against a due process challenge the National Childhood Vaccine Injury Act (“Vaccine Act”), holding that the Vaccine Act did not deprive litigants of a property interest when it prospectively abrogated tort claims arising out of administration of certain vaccines and replaced them with an exclusive remedy against the United States. *See Leuz v. Sec’y of Health & Hum. Servs.*, 63 Fed. Cl. 602 (2005). Relying on Fifth Circuit case law, the court held that “a plaintiff has no vested right in any tort claim for damages.” *Id.* at 610 (quoting *Ducharme*, 574 F.2d at 1309). As the court explained: “The Vaccine Act was the law of the land when petitioners’ cause of action arose. As such, the only property rights petitioners had to sue a manufacturer for alleged vaccine-related injuries necessarily flowed through the Vaccine Act. Because petitioners

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<sup>7</sup> *See Jones v. Wyeth Labs., Inc.*, 457 F. Supp. 35, 37 (W.D. Ark. 1978) (“No individual has a vested right in any common law cause of action. Any prospective cause of action Plaintiff may have had against a vaccine manufacturer had not vested at the time the Swine Flu Act was passed on August 13, 1976. Therefore, consistent with due process, the prospective cause of action could be abolished and the statutory remedy envisioned by the Swine Flu Act substituted.”) *aff’d*, 583 F.2d 1070, 1070-71 (8th Cir. 1978) (“We, thus, affirm on the basis of the District Court’s opinion.”); *Sparks v. Wyeth Labs., Inc.*, 431 F. Supp. 411, 416 (W.D. Okla. 1977) (“There is no question but that the Swine Flu Act comports with the due process clause of the Fifth Amendment. It is manifest that the statute, insofar as it abolishes a cause of action against a program participant, does so only prospectively.”); *Wolfe v. Merrill Nat. Labs., Inc.*, 433 F. Supp. 231, 236 (M.D. Tenn. 1977).

have not been deprived of any property right, they suffered no procedural due process violation.” *Id.* at 611. The same is true here. The PREP Act was the law of the land when Plaintiffs’ claims arose, so the PREP Act’s prospective grant of immunity for tort claims did not deprive them of any property right.

Indeed, courts have recognized that even when Congress passes a law abrogating then-pending causes of action and provides no substitute remedy, there has been no deprivation of a protected property interest. In 2005, Congress enacted the Protection of Lawful Commerce in Arms Act (“PLCAA”), which immunized federally licensed firearms manufacturers and sellers from most tort claims resulting from the criminal use of firearms, and applied even to pending claims, requiring courts to “immediately dismiss” such claims. *Ileto v. Glock, Inc.*, 565 F.3d 1126, 1131 (9th Cir. 2009) (quoting 15 U.S.C. § 7902(b)). Yet the Ninth Circuit held that plaintiffs suing firearms manufacturers had no “vested property right” in even a pending state-law cause of action, because “although a cause of action is a species of property, a party’s property right in any cause of action does not vest until a final unreviewable judgment is obtained.” *Id.* at 1141; *see also D.C. v. Beretta U.S.A. Corp.*, 940 A.2d 163, 175-76 (D.C. 2008) (similarly rejecting Due Process Clause challenge to PLCAA).

The case law cited by Plaintiffs is not to the contrary. Plaintiffs cite *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982), for the proposition that a cause of action is a type of property protected under the Due Process Clause. *Logan* held that a state violated the Fourteenth Amendment’s Due Process Clause when it deprived a plaintiff of a valid cause of action under state law because a state commission failed to convene a fact-finding conference during the time period required by the state statute. *Id.* at 427-31. But *Logan* explained that no due process violation occurs when the legislature changes or eliminates the rule of law that gave rise to the

cause of action, explaining: “the State remains free to create substantive defenses or immunities for use in adjudication—or to eliminate its statutorily created causes of action altogether—just as it can amend or terminate its welfare or employment programs. . . . In each case, the legislative determination provides all the process that is due.” *Id.* at 432-33.<sup>8</sup>

*Second*, Plaintiffs allege that “to the extent the PREP Act provides a right to relief for Plaintiffs and others injured by COVID-19 vaccines, Plaintiffs have a liberty or property interest in seeking proper relief for their injuries.” 2d Am. Compl. ¶ 138. But Plaintiffs do not allege that they have been deprived of the right to pursue CICP claims in accordance with the PREP Act. To the contrary, all five Plaintiffs have filed CICP claims and have had or are having those claims resolved in accordance with the PREP Act and applicable regulations. Ms. Burkey’s claim was found to be compensable, the claims of Ms. Bourque, Ms. Zimmerman, and Ms. Krogmeier are pending, 2d Am. Compl. ¶¶ 35, 79, 93, and Mr. Flint’s claim was denied (on initial decision and reconsideration, with both decisions occurring within two years of his claim submission) in accordance with the PREP Act and the governing regulations, *id.* ¶¶ 61, 63; Ex. 5.<sup>9</sup>

*Third*, Plaintiffs allege that there is a “liberty interest in pursuing an occupation,” and that their underlying physical “injuries” have limited their ability to work. *Id.* ¶ 139. But Plaintiffs do

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<sup>8</sup> None of the other cases cited by Plaintiffs upheld a challenge to a provision granting immunity for common-law claims. *See Tulsa Prof’l Collection Serv. v. Pope*, 485 U.S. 478, 485 (1988) (upholding challenge to state statute providing that probate claims could be extinguished if not presented to the executor within two months of publication of a notice of commencement of proceedings); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 806-12 (1985) (rejecting due process challenge to opt-out class actions); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 656 (S.D. Tex. 2004) (holding that a statute of limitations was reasonable and consistent with due process).

<sup>9</sup> Mr. Flint criticizes some of the reasoning in the decision denying his claim, *id.* ¶ 62, but he does not allege facts showing that there is “compelling, reliable, valid, medical and scientific evidence” that his injuries directly resulted from the vaccine, as would be necessary to establish a valid CICP claim. 42 U.S.C. § 247d-6e(b)(4).

not and cannot allege that Defendants (or the PREP Act) caused their physical injuries or took any other action to prevent them from pursuing an occupation. To whatever extent the interest in pursuing an occupation is protected under the Due Process Clause (which the Court need not decide), Plaintiffs allege no infringement of this interest by Defendants.

*Fourth*, Plaintiffs allege that Defendants have infringed a supposed “liberty interest” in “informed consent” to medical care. 2d Am. Compl. ¶ 140. But they allege no facts to support the conclusory allegation that the PREP Act or any action by Defendants have “eliminate[d] informed consent.” *Id.* They do not allege any way in which Defendants have altered informed consent requirements or required Plaintiffs to undergo any medical treatment against their will. Therefore, even if the Court were to assume that there exists a protected liberty interest in informed consent,<sup>10</sup> Plaintiffs have alleged no infringement of that interest.

## **2. Plaintiffs Fail To Identify Any Constitutional Infirmity In The CICP’s Procedures**

Plaintiffs’ due process claim fails at the first step, so the Court need not and should not advance to the second step of assessing the adequacy of the CICP’s procedures. But if the Court reaches that step, Plaintiffs fail to plead the existence of any constitutional inadequacy in the CICP procedures.

In an earlier status conference in this case, the Court noted that in the First Amended Complaint and the since-withdrawn Motion for Preliminary Injunction, Plaintiffs stated that they “believe CICP is an ineffective process,” but had not “enumerate[d] why such a process is a procedural due process violation.” *See* Minutes from Dec. 1, 2023 Status Conference, ECF No.

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<sup>10</sup> The Supreme Court has recognized that “a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment,” which in some instances can be infringed by forcible administration of medical treatment, *see Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 277 (1990), but the Supreme Court has not recognized a freestanding liberty interest in informed consent.

33, at 2-3. Plaintiffs have not cured this deficiency. The Second Amended Complaint raises criticisms of the CICP, acknowledges that “[p]erhaps each of these issues in isolation would not render CICP as violative of procedural due process,” but asserts that “taken together,” these criticisms “demonstrate the government’s disregard of basic due process protections.” 2d Am. Compl. ¶ 146. Yet Plaintiffs cannot show that any alleged feature of the CICP is unconstitutional, and they fail to explain how various constitutional features of the CICP somehow morph into a constitutional violation when “taken together.”

When assessing whether administrative procedures are constitutionally adequate, courts generally consider

three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

*Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

On the first factor, as explained above, Plaintiffs have not shown that any protected property interest is at stake, *see supra*, Part II.A.1. The crux of Plaintiffs’ argument is their contention that, at the second factor, the CICP employs unfair procedures that create a significant risk of erroneous denial of claims. But their allegations fail to show that such a significant risk exists.

Plaintiffs’ criticisms of the CICP are misguided and are either unsupported or are contradicted by their factual allegations and the statutes and regulations governing the CICP. Plaintiffs allege that only a small number of CICP claims based on COVID-19 countermeasures have been compensated, 2d Am. Compl. ¶ 99, but they plead no facts to support the inference of an “established record of erroneous” denials of CICP claims. *Id.*, heading before ¶ 145 (emphasis

and capitalization omitted). The CICIP's publicly reported data explains the status of CICIP claims and the reasons some claims have been denied. *See* HRSA, Countermeasures Injury Compensation Program (CICIP) Data, Aggregate Data as of January 1, 2024, <https://perma.cc/883K-PYFJ>.<sup>11</sup> As of January 1, 2024, 40 COVID-19 claims have been found eligible for compensation, including Ms. Burkey's claim (the majority of those eligible claims are currently awaiting determinations of the amount of benefits). Of the 2,174 COVID-19 claims that have been denied, 1,320 (60.7%) were denied as untimely, 340 (15.6%) were denied because the requester failed to submit requested medical records, 263 (12.1%) were denied based on failure to show that the person had suffered a covered injury directly caused by a covered countermeasure, and 251 (11.5%) were denied because the requester did not even identify any covered countermeasure that had been administered. Plaintiffs allege no facts to call into question the accuracy of these determinations.<sup>12</sup>

Plaintiffs complain that the "CICIP's process is shrouded in secrecy." 2d Am. Compl. ¶ 100. Yet they themselves cite four separate pages on CICIP's website, *see* [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp),

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<sup>11</sup> Plaintiffs affirmatively rely on an earlier iteration of this data and do not question its accuracy. *See* 2d Am. Compl. ¶ 99. Therefore, this data is fairly encompassed in the Second Amended Complaint and is subject to judicial notice. *See Doe*, 853 F.3d at 800 (court may consider "documents incorporated into the complaint by reference"); Fed. R. Evid. 201(b)(2) (court can take judicial notice of facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"). This data is available on the CICIP's website at <https://www.hrsa.gov/cicp/cicp-data>. Because the data is updated monthly, Defendants have provided a permanent link to the version of the data current as of the time of this filing.

<sup>12</sup> Plaintiffs criticize the denial of Mr. Flint's claim because a doctor told him "*I think* that shot made you one sick son of a bitch," and he allegedly suffered a "rapid onset of symptoms post-vaccination." 2d Am. Compl. ¶ 58 (emphasis added). But he does not allege facts showing that there is "compelling, reliable, valid, medical and scientific evidence" that his injuries directly resulted from the vaccine, as would be necessary to establish a valid CICIP claim. 42 U.S.C. § 247d-6e(b)(4). Allegations of timing of injury are insufficient because the governing regulations provide that "[t]emporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury." 42 C.F.R. § 110.20(c). Yet even if the Court believed that Plaintiffs had reasonably called into question the accuracy of a single claim determination, that would hardly establish that the program as a whole violates due process.

which describe CICIP's process. 2d Am. Compl. ¶¶ 101-02.<sup>13</sup> In addition to the information on the CICIP's website, HHS has issued regulations published in the Code of Federal Regulations that govern the CICIP's operations. *See* 42 C.F.R. Part 110. When HHS promulgated these regulations, HHS published notices that together comprised 37 pages in the Federal Register. *See Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule*, 75 Fed. Reg. 63,656 (Oct. 15, 2010); *Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Final Rule*, 76 Fed. Reg. 62,306 (Oct. 7, 2011). The publication of such extensive information about the CICIP's operations hardly indicates a program shrouded in secrecy.

Plaintiffs assert that they do not know who decides CICIP claims, 2d Am. Compl. ¶ 105, but eligibility determinations are made by the Director of the DICI (currently Dr. Grimes), and the Director issues signed letters explaining the basis of eligibility determinations. *See* 2d Am. Compl. Ex. 5 (decision letter signed by Dr. Grimes); 42 C.F.R. §§ 110.3(y), 110.73-110.74. Plaintiffs similarly assert they do not know who decides requests for reconsideration, but the regulations provide that reconsideration determinations are made by the Associate Administrator

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<sup>13</sup> CICIP's website contains pages generally describing the CICIP, <https://www.hrsa.gov/cicp>, describing the meaning of "covered countermeasures," <https://www.hrsa.gov/cicp/covered-countermeasures>; describing who can file for benefits, <https://www.hrsa.gov/cicp/who-can-file-benefits>; describing the CICIP's process, <https://www.hrsa.gov/cicp/filing-process>; describing the types of available CICIP benefits, <https://www.hrsa.gov/cicp/types-cicp-benefits>; describing the criteria used to determine whether a covered injury occurred, <https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred>; summarizing claims processing data, with ten monthly-updated Excel spreadsheets available for download, <https://www.hrsa.gov/cicp/cicp-data>; a frequently asked questions page with 40 questions and answers categorized by subject matter, <https://www.hrsa.gov/cicp/faq>; a chart comparing the CICIP to another compensation program, the Vaccine Injury Compensation Program, <https://www.hrsa.gov/cicp/cicp-vicp>; and a page collecting links to further resources, including the governing statute and regulations. <https://www.hrsa.gov/cicp/resources>. The website also lists a street address, email address, and toll-free telephone number for the CICIP.

of the Health Systems Bureau (currently Suma Nair, Ph.D., M.S.), after receiving a recommendation from a panel of qualified reviewers independent from the CICP. 42 C.F.R. § 110.90(c). The Associate Administrator explains her decisions in written letters that are “sent to the requester (or his or her representative).” *Id.*; *see also* 2d Am. Compl. ¶ 63 (indicating that Mr. Flint was notified of the denial of his request for reconsideration).

Plaintiffs assert that “they have no way to confirm whether any individuals deciding claims have any conflicts of interests.” 2d Am. Compl. ¶ 106. But as noted, the decisionmakers are the Director of the DICP (who makes initial determinations) and the Associate Administrator of the Health Systems Bureau (who makes reconsideration determinations), each of whom issued a signed decision letter to Mr. Flint. Plaintiffs allege no facts suggesting that these officials have a conflict of interest.

Plaintiffs complain that the government provides no definitive timeline for resolving claims, 2d Am. Compl. ¶ 107, but Mr. Flint received an eligibility decision in just over a year and Ms. Burkey received an eligibility decision in just over two years. That it would take some time for CICP to progress through COVID-19 claims is understandable, given that the program went from receiving only about 500 non-COVID-19 claims in its entire history to receiving a wave of around 13,000 COVID-19 claims over the last few years. *See* HRSA, Countermeasures Injury Compensation Program (CICP) Data, Aggregate Data as of January 1, 2024, <https://perma.cc/883K-PYFJ> (13,406 claims filed in CICP’s history, of which 12,854 are COVID-19 claims). As Plaintiffs’ own pleadings in this case reveal, the CICP has been increasing its pace

of resolving COVID-19 claims. *Compare* Compl. ¶ 153 (1,161 COVID-19 claims decided as of Sep. 1, 2023), *with* 2d Am. Compl. ¶ 99 (1,837 COVID-19 claims resolved as of Dec. 1, 2023).<sup>14</sup>

Indeed, pharmaceutical civil litigation, which Plaintiffs portray as the gold standard of due process, often takes far more than two years to resolve claims, particularly where (as here) hundreds or thousands of parties claim injury from the same products. As an example, a multidistrict litigation involving claims of more than 500 plaintiffs who claim to have suffered atypical femoral fractures caused by the drug Fosamax in the year 2010 or earlier has been pending for well over a decade, and is still involved in litigation over the preliminary question of whether plaintiffs' claims are preempted by federal law. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 593 F. Supp. 3d 96, 103-04 (D.N.J. 2022), *appeal pending*, No. 22-3412 (3d Cir.). As another example from this state, after six years, a multidistrict litigation involving the drug Taxotere only "beg[u]n the orderly process of remanding cases to their appropriate trial courts." Case Management Order No. 33, *In re: Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740 (E.D. La. Mar. 18, 2022). Plaintiffs cannot show that the length of time to resolve claims renders this administrative process constitutionally inadequate when the federal courts routinely take far longer to resolve similar claims.

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<sup>14</sup> Dr. Grimes recently testified to Congress that in response to the wave of COVID-19 claims, CICIP increased its staffing from four to more than thirty-five full-time staff members and made other process improvements to increase the pace of processing claims and enhance transparency, such as allowing requesters to check the status of claims online and introducing a chat function on its website. *See* Commander George Reed Grimes, Testimony before the United States House of Representatives, Committee on Oversight and Accountability, Select Subcommittee on the Coronavirus Pandemic (Feb. 15, 2024), *available at* [https://oversight.house.gov/wp-content/uploads/2024/02/HRSA\\_SSCP-Testimony-for-02.15.2024-Hearing.pdf](https://oversight.house.gov/wp-content/uploads/2024/02/HRSA_SSCP-Testimony-for-02.15.2024-Hearing.pdf). Congressional testimony is subject to judicial notice. *See, e.g., D.A.M. v. Barr*, 474 F. Supp. 3d 45, 55 (D.D.C. 2020) (taking judicial notice of congressional testimony); *Johnson & Johnson v. Am. Nat. Red Cross*, 528 F. Supp. 2d 462, 464 n.1 (S.D.N.Y. 2008) (same).

Plaintiffs acknowledge that the CICP has disclosed that to be covered, an injury must “direct[ly] result” from “the administration or use of a covered countermeasure,” and that “the CICP may only make such determinations based on compelling, reliable, valid, medical, and scientific evidence,” 2d Am. Compl. ¶ 109 (quoting <https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred>), but they argue that “[t]his standard appears to be determined by unidentified individuals,” *id.* Yet that standard comes directly from the governing statute. *See* 42 U.S.C. § 247d-6e(b)(1) (compensation available for “a covered injury directly caused by the administration or use of a covered countermeasure”); *id.* § 247d-6e(b)(4) (in absence of a covered countermeasure injury table, determinations of causation can be made “only . . . based on compelling, reliable, valid, medical and scientific evidence”). This standard is more favorable in key respects than the standard that would apply in tort litigation, where (depending on the exact cause of action) a plaintiff would need to prove additional elements, such as that a defendant was negligent or that the product was defective.

Plaintiffs complain that requesters cannot present fact or expert witnesses, 2d Am. Compl. ¶ 111, but the CICP regulations allow requesters to submit whatever written evidence they would like, including expert analysis. *See* 42 C.F.R. § 110.50. Requesters can also submit additional evidence at any time before an eligibility determination is made. *Id.* § 110.46(a). If the CICP needs additional information to resolve a claim, the program will inform the requester and give them a chance to submit the necessary documentation. *Id.* § 110.71.

Plaintiffs suggest that the CICP will lack funding to pay claims, 2d Am. Compl. ¶ 116, but the CICP has never failed to pay a compensable claim due to lack of funding, and Plaintiffs do not allege otherwise. Any notion that the CICP will run out of funding in the future and that Congress

will not provide funding necessary to pay claims is pure speculation and cannot support a present constitutional claim.

In sum, Plaintiffs fail to allege facts that would show that the CICP's procedures give rise to any meaningful risk of erroneous denials of claims, let alone a risk that is so significant as to be constitutionally unacceptable under the *Mathews* test.

The third *Mathews* factor directs courts to consider “the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.” *Mathews*, 424 U.S. at 335. This factor weighs against Plaintiffs because many of the changes sought by Plaintiffs would be incredibly burdensome, and others would be impossible for HHS to provide because they go beyond HHS’s statutory authority. Plaintiffs assert that they are only seeking “minimal due process protections,” 2d Am. Compl. ¶ 149, Prayer for Relief § 2, but they actually seek fifteen changes that would transform the CICP into civil litigation with full discovery, unlimited damages, trial by jury, and even a rule that *unsuccessful* claimants can obtain attorneys’ fees so long as their claim “was submitted in good faith and with a reasonable basis.” *Id.* ¶ 13. These proposed changes represent a vast departure from the current statutorily mandated structure for adjudicating CICP claims and would plainly be burdensome for HHS. Such changes would also make the process far more protracted, which would run counter to Plaintiffs’ claimed interest in having their claims resolved quickly. In addition, many of these changes are clearly beyond HHS’s statutory authority.<sup>15</sup> Simply put, the

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<sup>15</sup> For example, Plaintiffs propose lengthening the statute of limitations, 2d Am. Compl. ¶ 13.A, but the one-year deadline is statutory, *see* 42 U.S.C. § 247d-6e(b)(4) (incorporating procedures from 42 U.S.C. § 239a); 42 U.S.C. § 239a(d) (imposing one-year filing deadline). Plaintiffs propose allowing claimants to obtain recovery for all damages suffered and attorneys’ fees and costs, 2d Am. Compl. ¶¶ 13.L-M, but that would go beyond the compensation that Congress authorized the CICP to provide. *See* 42 U.S.C. §§ 247d-6e(b)(2); *see also id.* §§ 239c, 239d, 239e. Plaintiffs propose allowing judicial review of claim determinations, 2d Am. Compl. ¶ 17.N, but

Due Process Clause does not require Defendants to design the CICP according to Plaintiffs' exact specification, nor does it license this Court to do so.

**B. Plaintiffs Fail To Plead A Substantive Due Process Claim**

Plaintiffs' substantive due process claim is largely a repackaging of their procedural due process claim and fails for the same reasons. Substantive due process "protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (quotations and citations omitted). Plaintiffs do not and cannot show that there exists such a fundamental right to any particular procedure to obtain compensation for injuries, or a fundamental right that a common-law cause of action, once recognized, will never be altered by the legislature. Any such fundamental right would run counter to longstanding precedent holding that "[a] person has no property, no vested interest, in any rule of the common law. . . . Rights of property which have been created by the common law cannot be taken away without due process; but the law itself, as a rule of conduct, may be changed at the will . . . of the legislature, unless prevented by constitutional limitations." *Keller*, 441 F.2d at 1242 (quoting *Mondou*, 223 U.S. at 50).

As the Ninth Circuit has held, because a law granting immunity does not infringe fundamental rights, to satisfy substantive due process, it must only "withstand rational basis review," which it does "as long as the legislature was pursuing a rational policy." *Ileto*, 565 F.3d at 1140. Here, it was rational for Congress to provide liability immunity concerning countermeasures to incentivize development and deployment of countermeasures in public health emergencies, and provide those injured by countermeasures with an alternative remedy against the

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Congress has expressly precluded judicial review, *see* 42 U.S.C. § 247d-6e(b)(4); 42 U.S.C. § 239a(f)(2).

federal government, as Congress has done several times before. *See, e.g., Leuz*, 63 Fed. Cl. 602 (upholding act establishing Vaccine Injury Compensation Program against constitutional challenges, including substantive due process); *Ducharme*, 574 F.2d 1307 (upholding constitutionality of Swine Flu Act); Smallpox Emergency Personal Protection Act, Pub. L. No. 108-20, 117 Stat. 638 (2003) (codified at 42 U.S.C. §§ 239-239h) (establishing liability immunity and administrative compensation scheme for smallpox vaccines).

Plaintiffs cite two Supreme Court cases that they argue suggest that substantive due process requires that when legislation abrogates a common law tort claim, the legislature must offer a “just and reasonable substitute.” 2d Am. Compl. ¶ 157. But neither case held as such. In *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59 (1978), the Supreme Court strongly suggested that a statute abrogating tort claims presents no issue under the Due Process Clause. Although the Court noted that it had not definitively resolved the question, it stated that it was “not at all clear that the Due Process Clause in fact requires that a legislatively enacted compensation scheme either duplicate the recovery at common law or provide a reasonable substitute remedy,” because its “cases have clearly established that ‘[a] person has no property, no vested interest, in any rule of the common law,’ ” and “statutes limiting liability are relatively commonplace and have consistently been enforced by the courts.” *Id.* at 88 & n.32 (quoting *Mondou*, 221 U.S. at 50). In *New York Central Railroad Co. v. White*, 243 U.S. 188 (1917), the Supreme Court upheld a state statute that abrogated tort claims for workplace injuries, holding: “No person has a vested interest in any rule of law, entitling him to insist that it shall remain unchanged for his benefit.” *Id.* at 198. Although the Court noted that the statute replaced the abrogated tort claims with a workers’ compensation scheme that was “just,” *id.* at 202, it never held that a substitute remedy was constitutionally required. As noted, courts have upheld the PLCAA against due process challenges

even though that statute abrogated tort claims without providing any substitute remedy. Further, Congress provided a substitute remedy through the CICIP, so Plaintiffs' argument boils down to their erroneous procedural due process argument that the CICIP employs constitutionally inadequate procedures. *See supra*, Part II.A.2.<sup>16</sup>

Plaintiffs also argue that the one-year filing deadline violates due process. 2d Am. Compl. ¶¶ 163-68. Although this argument sounds in procedural due process rather than substantive due process, it fails in any event. As one of the cases cited by Plaintiffs explains, the length of a limitations period “must be settled by the judgment of the legislature, and the courts will not inquire into the wisdom of its decision in establishing the period of legal bar, unless the time allowed is manifestly so insufficient that the statute becomes a denial of justice.” *Wilson v. Iseminger*, 185 U.S. 55, 63 (1902). Here, Congress chose to impose a one-year deadline, *see* 42 U.S.C. § 247d-6e(b)(4) (incorporating procedural provisions from 42 U.S.C. § 239a); *id.* § 239a(d) (one-year filing deadline); *see also* 42 C.F.R. § 110.42(a), and Plaintiffs cannot show that this deadline is manifestly so insufficient as to constitute a violation of due process. Plaintiffs advance no reason why it is unreasonable for claimants to submit claims within a year of administration or use of a covered countermeasure. Here, all five Plaintiffs allege that they filed claims within this deadline, *see* 2d Am. Compl. ¶¶ 33, 54, 61, 74, 91, so nothing in their experience supports the contention that the filing deadline is so far beyond the pale of reason that it violates the constitution.<sup>17</sup>

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<sup>16</sup> Plaintiffs argue that “[m]any states provide a constitutional right to an alternative remedy” when a common law cause of action is abrogated. 2d Am. Compl. ¶ 159. But the Second Amended Complaint asserts no claim for violation of state constitutional rights. And as explained above, the CICIP provides reasonable access to a remedy.

<sup>17</sup> As explained above, because Plaintiffs were not harmed by the filing deadline, they also lack standing to challenge it. *See supra*, Part I.

Indeed, one-year limitations periods are common, which further undermines Plaintiffs' argument that this period is constitutionally insufficient. Louisiana has enacted a general one-year limitations period for most tort claims, La. Civ. Code Ann. art. 3492, including products liability and negligence claims, *see Bruno v. Biomet, Inc.*, 74 F.4th 620, 623 (5th Cir. 2023); *Copeland v. Wasserstein, Perella & Co.*, 278 F.3d 472, 478 (5th Cir. 2002). Louisiana courts have upheld this limitations period as consistent with due process. *See Picone v. Lyons*, 601 So. 2d 1375, 1377 (La. 1992); *Gauthreaux v. Rheem Mfg. Co.*, 588 So. 2d 723, 728 (La. Ct. App. 1991).<sup>18</sup> Likewise, the Antiterrorism and Effective Death Penalty Act imposes a one-year deadline on federal habeas corpus petitions, which the Fifth Circuit and other courts have upheld against constitutional attack. *See Molo v. Johnson*, 207 F.3d 773, 775 (5th Cir. 2000); *Miller v. Marr*, 141 F.3d 976, 977-78 (10th Cir. 1998).

### **C. Plaintiffs Fail To Plead A Violation Of The Seventh Amendment**

Plaintiffs also claim that the PREP Act violates their right to a jury trial under the Seventh Amendment. 2d Am. Compl. ¶¶ 170-89. It is not clear whether Plaintiffs are arguing that they have a right to a jury trial when pursuing monetary claims against the federal government under the CICP, or that they have a right to a jury trial in bringing tort claims against potential defendants who allegedly caused their injuries but enjoy immunity under the PREP Act. Either way, their claim fails as a matter of law.

Plaintiffs lack a Seventh Amendment right to a jury trial in their compensation claims against the United States because “[i]t has long been settled that the Seventh Amendment right to trial by jury does not apply in actions against the Federal Government.” *Lehman v. Nakshian*, 453 U.S. 156, 160 (1980). Indeed, “[i]t hardly can be maintained that under the common law in 1791

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<sup>18</sup> Louisiana courts have recognized a judicial discovery rule, but it “is only to be applied in extreme circumstances.” *Marin v. Exxon Mobil Corp.*, 48 So. 3d 234, 245 (La. 2010).

jury trial was a matter of right for persons asserting claims against the sovereign.” *Id.* (quoting *Galloway v. United States*, 319 U.S. 372, 388-89 (1943)); *see also* U.S. Const. amend. VII (amendment applies “[i]n suits at common law”). The inapplicability of the Seventh Amendment to claims against the federal government flows not just from constitutional text and history but also from “the general principle that the United States, as sovereign, is immune from suit save as it consents to be sued and the terms of its consent to be sued in any court define that court’s jurisdiction to entertain the suit.” *Lehman*, 453 U.S. at 160 (cleaned up). Therefore, “if Congress waives the Government’s immunity from suit, . . . the plaintiff has a right to a trial by jury only where that right is one of the terms of the Government’s consent to be sued. Like a waiver of immunity itself, [it] must be unequivocally expressed.” *Id.* (cleaned up). As the Fifth Circuit has flatly declared, “[w]hen the sovereign waives immunity it may attach any conditions (including no right to trial by jury) to its consent.” *Ducharme*, 574 F.2d at 1311; *see also Info. Res., Inc. v. United States*, 996 F.2d 780, 783 (5th Cir. 1993) (“the Seventh Amendment is inapplicable in actions against the United States”); *Mayo v. United States*, No. CIV. A. 98-0052, 1998 WL 877668, at \*4 (W.D. La. Nov. 25, 1998) (“The Seventh Amendment right to a jury trial does not apply in actions against the federal government.”). Although the PREP Act provides a limited waiver of the federal government’s sovereign immunity—allowing those who have suffered injuries to file administrative compensation claims against the federal government, *see* 42 U.S.C. § 247d-6e(b)(1)—it did not make trial by jury an “unequivocally expressed” term of that waiver, *Lehman*, 453 U.S. at 160. Therefore, Plaintiffs have no right to a jury trial when pursuing compensation under the CICP.

Plaintiffs provide no basis to disregard this clear precedent. Plaintiffs cite *Curtis v. Loether*, 415 U.S. 189 (1974), which holds that the Seventh Amendment entitles parties “to

demand a jury trial in an action for damages in the federal courts,” though generally not “in administrative proceedings,” *id.* at 192, 194. But because *Curtis* was a suit between private parties, there was no need for it to consider the precedent holding that the Seventh Amendment does not apply to claims for compensation from the federal government. *See id.* at 190.<sup>19</sup>

Plaintiffs also rely heavily on *Jarkesy v. SEC*, 34 F.4th 446 (5th Cir. 2022), *cert. granted*, 143 S. Ct. 2688 (2023) (argued Nov. 29, 2023), in which the Fifth Circuit held that a securities professional had the right to a jury trial when the Securities and Exchange Commission brought a proceeding against him for civil penalties based on violations of federal securities laws, *id.* at 451-59. *Jarkesy* has no application here because it concerns the scope of the jury trial right when the federal government initiates a proceeding against an individual seeking to impose penalties on that person, not the distinct question of whether a person has the right to a jury trial when pursuing monetary claims against the federal government. *Jarkesy* did not mention sovereign immunity and did not call into question the validity of longstanding Supreme Court and Fifth Circuit authority holding that a plaintiff has no right to a jury trial when pursuing relief from the federal government unless the federal government has unequivocally made the right to a jury trial a term of its waiver of sovereign immunity. *See Lehman*, 453 U.S. at 160; *Ducharme*, 574 F.2d at 1311. This Court therefore should reject Plaintiffs’ claim of a Seventh Amendment right to a jury trial when pursuing monetary claims against the federal government and need not decide how the Supreme Court’s “public rights” doctrine, as interpreted by the Fifth Circuit in *Jarkesy*, 34 F.4th at 453-57, might apply to the CICP.

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<sup>19</sup> Plaintiffs cite a passage from *Parsons v. Bedford*, 28 U.S. 433, 447 (1830), that is part of the argument of counsel, not the Court’s opinion. The opinion of the Court, which held that the Seventh Amendment extends to actions in federal court under Louisiana law involving private parties even though Louisiana has a civil law system, is not relevant here. *See id.* at 448-49.

Furthermore, accepting Plaintiffs’ arguments would have wide-ranging and troubling consequences. When Congress waives sovereign immunity to allow parties to pursue monetary compensation against the federal government, it generally *does not* include the right to a jury trial in such waiver, instead leaving such claims to be adjudicated in administrative tribunals, specialized federal courts such as the Court of Federal Claims without a jury, or in federal district court without a jury.<sup>20</sup> Even if Plaintiffs’ arguments were not squarely foreclosed by binding precedent, the Court should be wary of upending historical practice by holding that Congress cannot waive sovereign immunity for arguably tort-like claims without triggering a right to a jury trial—a decision that could have profound implications for Congress’s willingness to create compensation funds like the CICP in response to future crises.

To the extent Plaintiffs claim that they have been deprived of a jury trial for tort claims against the unspecified individuals or entities who allegedly caused their injuries, that argument fails as well because the PREP Act validly granted immunity from claims. “The ‘Constitution does not forbid the creation of new rights, or the abolition of old ones recognized by the common law, to attain a permissible legislative object,’” and “statutes limiting liability are relatively commonplace and have consistently been enforced by the courts.” *Duke Power*, 438 U.S. at 88 n.32 (quoting *Silver v. Silver*, 280 U.S. 117, 122 (1929)). “[A]s a matter of logic, it is axiomatic

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<sup>20</sup> See, e.g., Pub. L. No. 107-42, §§ 401-409, 115 Stat. 230 (2001) (establishing the September 11 Victim Compensation Fund to allow victims of the September 11, 2001, terrorist attacks to bring compensation claims before a special master); Tucker Act, 28 U.S.C. § 1491 (waiving sovereign immunity and providing jurisdiction in the Court of Federal Claims for certain tort claims against the federal government); *Gonzalez-McCaulley Inv. Grp., Inc. v. United States*, 93 Fed. Cl. 710, 713 n.1 (2010) (explaining that “[t]here are . . . no jury trials in the Court of Federal Claims”); Little Tucker Act, 28 U.S.C. § 1346(a)(2) (providing for concurrent jurisdiction in the Court of Federal Claims and federal district courts for certain civil claims against the United States not exceeding \$10,000); *id.* § 2402 (“any action against the United States under section 1346 shall be tried by the court without a jury”).

that if a cause of action can be abolished, the jury trial of that action is also abolished.” *Sparks*, 431 F. Supp. at 418. “[T]he Government can legislate the rights of action out of existence and substitute an exclusive remedy against” the federal government, “notwithstanding that it precludes a jury trial.” *Adams v. Jackel*, 220 F. Supp. 764, 766 (E.D.N.Y. 1963). Indeed, the Fifth Circuit has specifically rejected a Seventh Amendment claim where Congress eliminated tort claims and replaced them with a remedy against the United States with no jury trial. *See Ducharme*, 574 F.2d at 1311.

#### **D. Plaintiffs Lack A Valid Claim For A Declaratory Judgment**

Finally, Plaintiffs purport to bring a separate claim titled “Declaratory Judgment,” in which they argue that they “are entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201.” 2d Am. Compl. ¶ 129. However, “the Declaratory Judgment Act alone does not create a federal cause of action.” *Harris Cnty. Texas v. MERSCORP Inc.*, 791 F.3d 545, 552 (5th Cir. 2015). “[T]he [Declaratory Judgment] ‘enlarged the range of remedies available in the federal courts,’ but it did not create a new right to seek those remedies.” *Id.* (quoting *Skelly Oil Co. v. Phillips Petrol. Co.*, 339 U.S. 667, 671 (1950)). Plaintiffs claim entitlement to a declaratory judgment because the PREP Act purportedly “violate[s] the Fifth and Seventh Amendments,” 2d Am. Compl. ¶ 129, the same arguments pursued in the Second Amended Complaint’s substantive counts. Because those substantive counts fail to plead a valid claim, *see supra*, Parts II.A-C, Plaintiffs have failed to plead entitlement to a declaratory judgment.

#### **CONCLUSION**

For the foregoing reasons, the Court should dismiss Plaintiffs’ Second Amended Complaint for lack of subject-matter jurisdiction and failure to state a claim.

Dated: February 20, 2024

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

**I HEREBY CERTIFY** that on February 20, 2024, a copy of the foregoing was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the Court's electronic filing system.

/s/Jeremy S.B. Newman

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